

SmartPA Criteria Proposal

Drug/Drug Class:	Neuromyelitis Optica Spectrum Disorder (NMOSD) Clinical Edit
First Implementation Date:	TBD
Proposed Date:	December 17, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input checked="" type="checkbox"/> New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of agents for neuromyelitis optica spectrum disorder (NMOSD)

Why Issue Selected: Neuromyelitis optica spectrum disorder (NMOSD) is a rare, autoimmune disease of the central nervous system that primarily attacks the optic nerves and spinal cord resulting in inflammation of the optic nerve (optic neuritis) and spinal cord (myelitis) leading to accumulating neurological damage and disability. NMOSD is characterized as repeated acute attacks separated by periods of remission that may be weeks, months, or years in length. NMOSD is very commonly confused with multiple sclerosis; only within the last 10 years has NMOSD become differentiated from multiple sclerosis due to the discovery of the anti-aquaporin-4 (AQP4) antibody which is now an identifier of the disease. It is estimated that 10,000 patients in the United States have NMOSD with 8,000 cases being anti-AQP4 antibody positive.

Uplizna™ (inebilizumab-cdon), a CD19-directed cytolytic antibody, was FDA approved in June 2020, for the treatment of NMOSD in adult patients who are anti-AQP4 antibody positive. Uplizna is given as a 300 mg IV infusion over 90 minutes. The first infusion is followed by another 2 weeks later; then subsequent dosing is every 6 months (beginning 6 months after the first infusion). Premedication with a corticosteroid, antihistamine, and antipyretic is required prior to every infusion.

Enspryng™ (satralizumab-mwge), an interleukin-6 (IL-6) receptor antagonist, was FDA approved in August 2020, for the treatment of NMOSD in adult patients who are anti-AQP4 antibody positive. Enspryng is the first self-administered subcutaneous therapy to be approved for NMOSD. It is administered as a loading dose of 120 mg by subcutaneous injection at weeks 0, 2, and 4, followed by a maintenance dose of 120 mg every 4 weeks.

Due to the high cost and specific approved indication, MO HealthNet will impose clinical criteria to ensure appropriate utilization of agents for NMOSD.

Program-Specific Information:	Date Range FFS 10-1-2019 to 9-30-2020			
	Drug	Claims	Cost per unit	Cost per year at maintenance dose
	ENSPRYNG 120 MG/ML SYRINGE	0	\$14,615.39 MAC	\$190,000.07 MAC
	UPLIZNA 100 MG/10 ML VIAL	0	\$43,666.67 MAC	\$262,000.00 MAC

Type of Criteria: Increased risk of ADE Preferred Drug List
 Appropriate Indications Clinical Edit

Data Sources: Only Administrative Databases Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Agents for neuromyelitis optica spectrum disorder (NMOSD)
- Age range: All appropriate MO HealthNet participants aged 18 years and older

Approval Criteria

Initial Therapy:

- Participant is aged 18 years or older **AND**
- Prescribed by or in consultation with an immunologist, neurologist, or other specialist within the treated disease state **AND**
- Documented diagnosis of neuromyelitis optica spectrum disorder (NMOSD) **AND**
- Participant is seropositive for anti-aquaporin-4 (AQP4) antibodies **AND**
- Participant is not currently pregnant **AND**
- Participant (female of appropriate age) is utilizing concurrent birth control methods **AND**
- Documented baseline number and frequency of acute attacks **AND**
- For Uplizna: documented therapeutic trial of Enspryng (trial defined as at least 6 months of therapy)

Continuation of Therapy:

- Initial approval is for 9 months, renewal of prior authorization may be for up to 12 months following documentation of decrease or stabilization in number and frequency of acute attacks from baseline

Denial Criteria

- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results: Progress Notes:
 MedWatch Form: Other:

Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)
 Rule Type: CE

Default Approval Period

9 months

References

- Enspryng™ (satralizumab-mwge) [package insert]. San Francisco, CA: Roche, Inc; August 2020.
- Uplizna™ (inebilizumab-cdon) [package insert]. Gaithersburg, MD: Viela Bio; June 2020.
- IPD Analytics. New Drug Review: Uplizna (inebilizumab-cdon). June 2020.
- IPD Analytics. New Drug Review: Enspryng (satralizumab-mwge). September 2020.
- Kessler R.A, Mealy M.A, et al. Treatment of Neuromyelitis Optica Spectrum Disorder: Acute, Preventive, and Symptomatic. *Curr Treat Options Neurol*. 2016;18(1):2. doi: 10.1007/s1140-015-0387-9.
- National Organization for Rare Disorders (NORD). Neuromyelitis Optica Spectrum Disorder. <https://rarediseases.org/rare-diseases/neuromyelitis-optica/>. Accessed September 2, 2020.

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